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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,920	05/23/2001	Daniele Piomelli	07306-019001 / 2000-202-1	1684

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,920

Applicant(s)

PIOMELLI, DANIELE

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 17,18,33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Claims 17, 18, 33 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Applicant's election without traverse of claims 1-16 and 19-32 in Paper No. 9 is acknowledged.

Claims 1-16 and 19-32 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 and 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 and 19-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: as follows:

The structures of the above claims are not completely searchable. The term hydrocarbonyl (as in R is a saturated or unsaturated, chiral or achiral, cyclic or acyclic,

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substituted or unsubstituted hydrocarbyl group with 11 to 29 carbon atoms. There is insufficient information given to search this claim. The term hydrocarbyl means univalent groups formed by removing a hydrogen atom from a hydrocarbon, e.g. ethyl, phenyl. The meaning of this term is unclear with the regard to the above R group. Claim 2 recites the method of claim 1 wherein the R comprises 1 to 6 oxygen or sulfur atoms. This is structurally unsearchable. Claim 4 is illogical as it relates to claim 3 in that it is unclear where the R₂ is in the oxazolidinone ring and the morpholine ring. Claim 8 recites the structure of formula III wherein R is a saturated or unsaturated, substituted or unsubstituted hydrocarbyl group with from 15 to 29 carbon atoms. This is not searchable. Claim 6, which recites the method of claim 5 wherein R comprises 1 to 3 oxygen or sulfur atoms, is structurally unsearchable. Claim 9, which recites the method of claim 8 wherein R comprises 1 to 3 oxygen or sulfur atoms, is structurally unsearchable. Claim 10 recites the structure of formula IV wherein R is a saturated or unsaturated, substituted or unsubstituted hydrocarbyl group with from 18 to 22 carbon atoms. This is not searchable. Claim 12 recites the structure of formula V wherein R is a saturated or polyunsaturated, substituted or unsubstituted hydrocarbyl group with from 6 to 22 carbon atoms. This is not searchable.

The remaining claims are indefinite to the extent that they read on the rejected base claims.

The instant application is searched based on the compounds recited in claims 19-21.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-16 and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stengel et al. European Journal of Pharmacology (U).

The claims are drawn to a method of ameliorating cough comprising administration of inter alia anandamide by local administration to the upper airways, or systemic administration.

Stengel et al. teach anandamide may possess minimal direct airway smooth muscle related actions and it may possess modest anti-inflammatory properties. Anandamide was tested to reverse chemical induces airway restriction in guinea pigs. It was found to be mildly effective (see abstract). The rejection is made under 35 USC 103(a) because it is unclear which claims read on the anandamide compound since the structure claims appear to be unsearchable. However, It is prima facie obvious to

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substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Such a modification would have been motivated by the reasoned expectation of producing a cannabinoid type composition which is effective in comprehensively treating persons suffering from cough/asthma.

2. Claims 1-16 and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over British Medical Association, Therapeutic Uses of Cannabis, 1997(V).

The excerpt provided teaches that acute doses of cannabis and tetrahydrocannabinol (THC) exert a definitive bronchodilator effect on the small airways of the lungs. The mechanism is not known, but it appears to be different from that of other drugs used at present as bronchodilators for asthma. Smoked cannabis was also capable of reversing experimentally induced bronchospasm in three asthmatic subjects. The rejection is made under 35 USC 103(a) because it is unclear which claims read on the THC compound since the structure claims appear to be unsearchable. However, it is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Such a

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modification would have been motivated by the reasoned expectation of producing a cannabinoid type composition which is effective in comprehensively treating persons suffering from cough/asthma.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe
Patent Examiner
Art Unit 1614

April 7, 2003